

510(k) Summary

AUG - 2 2007

Manufacturer: Small Bone Innovations International, SA  
Z.A. Les Bruyeres  
Peronnas France 01960

Submitted By: Small Bone Innovations  
1380 South Pennsylvania Avenue  
Morrisville, PA 19067

Proprietary Name: SBi StaFIX

Classification name: Class II, 888.3030 – Single/multiple component metallic  
bone fixation appliances and accessories

Common/Usual Name: Staple, Fixation, Bone

Product Code: JDR

Substantial Equivalence: Documentation is provided which demonstrated the SBi  
StaFIX to be substantially equivalent to other legally  
marketed devices.

Device Description: The SBi StaFIX System consists of a set of stainless steel  
staples for internal fixation. The devices are supplied  
non-sterile and are available in several configurations  
and sizes.

Intended Use: The SBi StaFIX is indicated for:

- Fixation of fractures, osteotomies, and arthrodesis  
(fusion) in long and small bones.
- Fixation of soft tissue to bone

Material: The implants are made from 316L Stainless Steel in  
accordance with ISO 5832-1.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG - 2 2007

Small Bone Innovations, Inc.  
% Mr. James O'Connor  
VP, QA/QC & Regulatory Affairs  
1380 South Pennsylvania Avenue  
Morrisville, PA 19067

Re: K071479  
Trade/Device Name: SBi StaFix  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation  
appliances and accessories  
Regulatory Class: Class II  
Product Code: JDR  
Dated: May 25, 2007  
Received: May 29, 2007

Dear Mr. O'Connor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

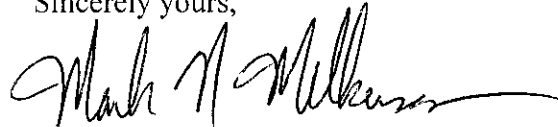
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K071479

## Indications for Use

510(k) Number:

Device Name: SBi StaFIX

Indications For Use:

The SBi StaFIX is indicated for:

- Fixation of fractures, osteotomies, and arthrodesis (fusion) in long and small bones.
- Fixation of soft tissue to bone

Prescription Use ☒  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☒  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1



(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number

K071479